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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/608,200	06/30/2000	Michael J. Banner	21011.0038U1	1062

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EXAMINER

PATEL, MITAL B

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/608,200

Applicant(s)

BANNER ET AL

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the actuator must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because reference characters 30, 32, 34, and 36 are pointing to the same structural element. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "52" has been used to designate both one sensor and plurality of sensors. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and **legal phraseology** often used in patent claims, such as "means" and "said," **should be avoided**. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. There is a lack of antecedent basis for the following limitations:

- Claim 19, line 6, "the current level setting"
- Claim 19, lines 11-12, "the measured ventilation support parameter"
- Claims 20 and 32, line 2, "the flow rate"
- Claims 20 and 32, line 3, "the exhaled carbon dioxide"
- Claims 20 and 32, line 5, "the hemoglobin oxygen saturation level"
- Claims 20 and 32, line 5, "the pressure of the breathing gas"
- Claims 20 and 32, line 6, "the blood pressure"
- Claims 20 and 32, line 7, "the core body temperature"
- Claim 21, line 2, "the arterial blood gas PaO<sub>2</sub> level"

- Claim 21, line 3, "the arterial blood gas PaCO<sub>2</sub> level"
- Claim 21, line 3, "the arterial blood gas pH level"
- Claim 32, line 6, "the current level setting"
- Claim 33, line 2, "the desired level settings"
- Claim 34, line 1, "the desired level setting"
- Claim 35, lines 3-4, "the portion of the ventilation data and the portion of the ventilator setting parameter"
- Claim 36, line 2, "the desired level settings"
- Claim 38, line 3, "the desired level setting"

Correction is required.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Biondi et al (US 6158432).

10. **As to claim 19**, Biondi teaches a ventilator for supplying a breathing gas to a patient via a breathing circuit in fluid communication with the ventilator and at least one lung of a patient, the ventilator **17** having a plurality of selectable ventilator setting controls **10** for governing the supply of a breathing gas from the ventilator to the patient, each setting control selectable to a level setting, and each ventilator setting control generating a ventilator setting parameter signal indicative of the current level setting of the ventilator setting control; an input **26** that receives at least one ventilator setting parameter signal; a plurality of sensors **19, 11, 9, 7** for measuring a plurality of ventilation support parameters, each sensor operatively connected to a selected one of the patient or the breathing circuit, wherein each sensor generates an output signal based on the measured ventilation support parameter; a processing subsystem connected to receive output signals from the sensors and the ventilator setting parameter signal from the ventilator setting control, the processing subsystem having a processor **30, 31, 32** and a memory **15**, the processor running under control of a program stored in the memory, the processing subsystem having an intelligence system (**Col. 5, lines 30-42**) to determine a desired level setting of at least one ventilator setting control in response to the ventilator setting parameter signal and the output signals.

11. **As to claims 20, 21, 22 and 25**, Biondi teaches the particulars as recited in the claims. (See Col. 11).
12. **As to claim 23**, Biondi teaches a ventilator further comprising a display **12, 24**, wherein the processing subsystem provides the level settings of the ventilator setting controls to the display.
13. **As to claim 24**, Biondi teaches a ventilator further comprising an alarm for notifying an operator of the ventilator that the level settings of the ventilator setting controls differs from the determined desired level settings of the ventilator setting controls.
14. **As to claim 26**, Biondi teaches a ventilator wherein the processing subsystem has at least one neural network **212** and the processor in determining the desired level setting of the ventilator setting controls, generated a plurality of ventilation data from the output signals of the sensors and applies at least a portion of the ventilation data and at least a portion of the ventilator setting parameter signals to the neural network to determine the desired level setting of the ventilator setting controls.
15. **As to claim 27**, Biondi teaches a ventilator wherein the processing subsystem is programmed with a set of decision rules **142, 144** and wherein the processor applies the set of decision rules to the ventilation data prior to applying the portion of the ventilation data and the portion of the ventilator setting parameter signal to the neural network.
16. **As to claim 28**, Biondi teaches a ventilator further comprising a display, wherein the processing subsystem identifies ventilation data used to determine the desired level

setting controls, identifies a subset of the ventilation data for display, and provides the subset of the ventilation data to display, and wherein the processing subsystem provides the desired level settings of the ventilator setting controls to the display.

17. **As to claim 29**, Biondi teaches a ventilator wherein the processing subsystem has at least one neural network **212**, the neural network under control of a program stored in the memory, and wherein the determining means of the processing subsystem comprises means for generating ventilation data from output signals of the sensors; means for selecting at least a portion of the ventilation data and at least a portion of the ventilator setting parameter signals; means for converting the selected ventilation data and the selected portion of the ventilator setting parameter signals into a plurality of numerical expressions; means for transforming each of the numerical expressions into a number in a predetermined range; and means for inputting a plurality of the transformed numerical expressions into the neural network so that the desired level settings of the ventilator setting controls are determinable in accordance with the input numerical expressions (**Col. 6, lines 54-67, Col. 17, and Col. 18, lines 1-8**).

18. **As to claim 30**, Biondi teaches a ventilator wherein the processing subsystem has at least one neural network **212** under control of a program stored in the memory and wherein the determining means of the processing subsystem comprises means for generating a plurality of training data sets, each training data set including output signals of the measured ventilation support parameters and indicated level settings of the ventilator setting controls associated with a historical occurrence of physiologic conditions of the patient during ventilation support; means for training the neural



network using the statistically significant training data sets so that the desired level settings of the ventilator setting controls are determined based upon selected output signals and selected level settings of the ventilator setting controls (**Col. 6, lines 54-67, Col. 17, and Col. 18, lines 1-8**).

19. **As to claim 31**, Biondi teaches a ventilator for supplying a breathing gas to a patient via a breathing circuit in fluid communication with at least one lung of a patient, the ventilator having a plurality of ventilator setting controls **10** governing the supply of the breathing gas from the ventilator to the patient, each ventilator setting control selectable to a level setting, and each ventilator setting control generating a ventilator setting parameter signal indicative of the current level setting of the ventilator setting control, the system comprising an input **26** that receives at least one ventilator setting parameter signal; a plurality of sensors **19, 11, 9, 7** for measuring a plurality of ventilation support parameters, each sensor generating an output signal indicative of the measured ventilation support parameter, a processing subsystem having a neural network **212** that receives data, and a processor **30, 31, 32** having a memory **15**, the processor connected to receive the output signals from the sensors and the ventilator setting parameter signal from the input and running under control of a program stored in the memory to generate ventilation data from the output signals, to apply at least a portion of the ventilation data and at least a portion of the ventilator setting parameter signals to the neural network to determine desired level settings of the ventilator setting controls.

20. **As to claims 32 and 34**, Biondi teaches the particulars as recited in the claims.  
(See Col. 11).

21. **As to claim 33**, Biondi teaches a ventilator further comprising a display **12, 24**, wherein the processing subsystem provides the desired level settings of the ventilator setting controls to the display.

22. **As to claim 35**, Biondi teaches a ventilator wherein the processor is programmed with a set of decision rules **142, 144** and wherein the processor applies the set of decision rules to the ventilation data prior to applying the portion of the ventilation data and the portion of the ventilator setting parameter signal to the neural network.

23. **As to claim 36**, Biondi teaches a ventilator further comprising a display, wherein the processing subsystem identifies ventilation data used to determine the desired level setting controls, identifies a subset of the ventilation data for display, and provides the subset of the ventilation data to display.

24. **As to claim 37**, Biondi teaches a ventilator wherein the processing subsystem has means for training the neural network.

25. **As to claim 38**, Biondi teaches a ventilator further comprising an alarm for indicating to a user of the ventilator that the level settings of the ventilator setting controls has been adjusted the alarm comprising a selected one of an audible alert or a visible alert, wherein the alarm responsive to the response signal.

26. **As to claims 1-18**, the method claims are equivalent in scope to the apparatus claims 20-40 as taught by Biondi, i.e., the method steps are inherent in using the apparatus of Biondi as set forth above.

### ***Double Patenting***

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

28. Claims 1-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No.

09/607713. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are merely broader than those recited in the copending application.

**Conclusion**

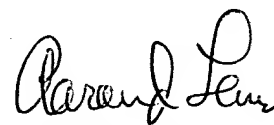
29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6369838, US 6305372, US 6206001, US 6158430, US 5931160, US 5927274, US 5915380, US 5915379, US 5678539, and US 5320093.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on 703-308-4304. The fax phone numbers for the organization where this application or proceeding is assigned are 703-306-4520 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

mbp  
October 1, 2002

  
Aaron J. Lewis  
Primary Examiner

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